

# Responding to FDA Enforcement

An integrated approach to process improvements and compliance remediation yields lasting benefits

## Rapid Response to FDA Enforcement Actions

As the FDA ratchets up its enforcement actions, pharmaceutical and medical device companies are turning to Quintiles. Our team of ex-FDA officials and industry experts helps clients respond with unique and effective strategies to restore client credibility with the FDA, as well as strengthen client processes with cost-effective approaches.

## What differentiates the consulting solutions offered by Quintiles from other consulting firms?

- > *Uniquely focused on resolving FDA enforcement actions through our extensive knowledge of quality systems, coupled with management consulting expertise*
- > *Track record of successful remediation, resolving Warning Letters and establishing foundations for sustained compliance*
- > *Unparalleled experience working with virtually every major biopharma and medical device company across the globe*
- > *An unmatched combination of former FDA officials, industry experts and management consultants*

## Representative Service Offerings

- > *Providing strategic consultation regarding quality systems and GMP/QSR compliance*
- > *Performing Mock FDA Inspections and FDA Preparedness Training*
- > *Developing and implementing quality systems for pharma / medical device / biotech clients*
- > *Conducting GMP/QSR assessments*
- > *Developing and executing validation programs*
- > *Developing and implementing corrective action plans*
- > *Assisting in response to FDA enforcement actions*
- > *Investigating suspected fraud and scientific misconduct*
- > *Presenting GMP/QSR training*

### CASE STUDY: Averting a Major Recall

**Company:** Multi-national pharma / device manufacturer

**Challenge:** Identifying the root cause of a breached seal in a sterile package that resulted in product line recalls and the potential to further damage the company.

**Quintiles Response:** Quintiles used a rigorous approach in its Design of Experiments (DOE) to analyze the process parameters and isolate the root cause.

**Impact:** A root cause approach was used to isolate the problem, and changes were implemented to resolve it. Extensive review showed that the other packages met requirements. A major recall was averted, saving millions of dollars.

## More than 500 Experts at Your Service

The largest complement of industry, FDA and management consulting experts, led by seasoned professionals.

### Robert A. Rhoades

Bob has more than 34 years of experience in quality management in FDA-regulated industry. Known for his counsel to industry executives in such matters as the worldwide heparin contamination crisis in 2008, Bob has successfully managed Warning Letter resolutions for both US and foreign companies, and is currently leading the consulting effort for one of the FDA's most severe enforcement actions in history.

### Brad Dawson

Brad leads client initiatives in Process-Driven Compliance, focused on Reduced Costs & Process Complexity and Improved Development Operational Efficiency. A 15-year veteran of management consulting for major life sciences clients, Brad has also worked on a collaborative research initiative with the FDA's Office of Pharmaceutical Science, CDER, focused on the current state practices of pharmaceutical R&D with an aim to identify collaborative opportunities with FDA to improve performance and minimize risk.

### Kristen Grumet

Kristen offers a unique blend of more than nine years as a Field Investigator for the FDA, plus management responsibility for quality systems compliance within the medical device industry. She was among the first cadre of certified medical device investigators in FDA history, as well as a member of FDA's Foreign Inspection Cadre, and now leads many client initiatives in the medical device industry. Kristen recently led a program that successfully completed the certification of a post-Consent-Decree quality system for a major medical device manufacturer.

### Michael Levitt

A veteran operations executive with over 30 years in the industry, Mike brings experience from pharma companies like Eli Lilly and Company and Solvay Pharmaceuticals, small biotech and large-scale project management such as the recent refitting and successful qualification of a major manufacturer's vaccine facility. Mike managed a \$250 million budget, and his team achieved two first-pass zero-438 inspections by FDA.

### Marie R. McDonald

Marie brings to her engagements 15 years of experience consulting for biopharma and medical device companies on strategy, program and project planning, process design, training and change management. Her client work at Quintiles focuses largely on quality systems evaluation, process improvement and technology implementation, as well as, regulatory remediation and compliance improvement.

#### Contact Us:

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## CASE STUDY: FDA Warning Letter Response – Third-Party Verification

**Company:** Multi-national pharma / device manufacturer

**Challenge:** Provide third-party verification of batch records and investigations process for parenterals plan to restore FDA confidence in client's ability to release product, and investigate lab and manufacturing deviations adequately. As a result of the Warning Letter, the first had stopped production of a key product group on the FDA Drug Shortage List.

**Quintiles Response:** Leveraging experience across many disciplines, Quintiles experts were able to determine the root cause of key manufacturing deficiencies and establish new, efficient processes for plant management to restore compliance.

**Impact:** The root cause of the problem was resolved and validated, and the product supply was renewed. With new CAPA processes in place, the fully optimized system eliminated the backlog of investigations and can be rolled out on a corporate level to assure global consistency and control.

## CASE STUDY: Quality System Remediation

**Company:** Global medical device company

**Challenge:** Third-Party Certification of the company's quality system was required in order to resume distribution of one of its primary product lines following issuance of a Consent Decree.

**Quintiles Response:** Quintiles' Core Team Process was applied to systematically evaluate and improve each of the eight subsystems comprising the company's quality system. The team provided project oversight and partnered with each of the subsystem teams to provide the guidance and regulatory expertise needed to address the compliance challenges.

**Impact:** Third-Party Certification was achieved in accordance with the Consent Decree. The improvements resulted in the development of a global Quality System that is compliant, efficient and adaptable to all of the company's multiple medical device divisions.

